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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,484	02/28/2000	DEBORAH A SCHADE	MJ-729	4022

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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/381,484	SCHADE ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The request filed on February 19, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/381,484 is acceptable and a CPA has been established. An action on the CPA follows.

Specification Objection

2. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

Claim Rejections 35 U.S.C. § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "suitable" in claim 14 is a relative term which renders the claim indefinite. The term "suitable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim is indefinite as to the meaning of "suitable".

Claim Rejections 35 U.S.C. § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by a well established common practice, breast feeding premature infant, in view of Crozier G.L. et al. (Monatschrift Für Kinderheilkunde, Vol. 143, No. 7, 1995, page 95-98, with English translation, IDS) and Kyle (U.S. Patent 5,374,657).

8. The claims read on breast-feeding premature infant. Crozier G.L. et al. discloses that breast milk containing sufficient amounts of DHA and ARA to help premature infant growth health. See, the English translation, page 5, the second and third paragraph. Kyle teaches that the ratio of ARA and DHA in breast milk is about 3:1. See, e.g., table 6 in column 16.

9. Claims 14-16 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kyle (U.S. Patent 5,374,657), in view of Crozier G.L. et al. (Monatschrift Für Kinderheilkunde, Vol. 143, No. 7, 1995, page 95-98, with English translation, IDS) and McGraw-Hill Encyclopedia of Food, Agriculture & Nutrition.

10. Kyle teaches an infant formula comprising DHA and ARA in comparable amounts of DHA and ARA in human breast milk. The ratio of ARA:DHA is about 3:1. The concentration is about 177 mg/L of ARA and 57 mg/L of DHA. See the claims and the examples in columns 13-16. It is known that breast milk would provide sufficient ARA and DHA to the infant. (Daily intake 175 ml/kg breast milk for the infant). The amounts would fall within the scope of claimed amounts in claims 18 and 19. See, Crozier, the English translation, page 5; the second and third paragraph. Note the daily calorie of infant is known to be about 100-120 kcal/kg. See McGraw-Hill Encyclopedia of Food, Agriculture & Nutrition, page 159.

Claim Rejections 35 U.S.C. § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-8, 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle (U.S. Patent 5,374,657) in view of Crozier G.L. et al. (Monatschrift Für Kinderheilkunde, Vol. 143, No. 7, 1995, page 95-98, with English translation, IDS).

13. Kyle teaches an infant formula comprising DHA and ARA in comparable amounts of DHA and ARA in human breast milk. The ratio of ARA:DHA is about 3:1 to 2:1. See the claims and the examples in columns 13-16. Kyle also teaches that the presence of ARA and DHA in infant food is critical for a healthy growth for infants. See, particularly, column 1, lines 29-53.

14. Kyle does do teach expressly the administration of the infant formula to preterm infants, or the particular ratio of ARA: DHA, and the particular amounts of ARA: DHA herein.

15. However, Crozier et al. teaches that the presence of ARA and DHA in food is particularly important for preterm infants to proper growth and development because they are unable to synthesize sufficient ARA and DHA. See, particularly, the summary. Crozier et al. further teaches that breast milk would provide sufficient ARA and DHA to preterm infants.

16. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the infant formula of Kyle for feeding preterm infants.

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17. A person of ordinary skill in the art would have been motivated to employ the infant formula of Kyle to preterm infants because preterm infants are known to be in need of food with sufficient amount of ARA and DHA and formula of Kyle is known to containing about the same amount of ARA and DHA as breast milk. Further, optimization of the amounts of ARA and DHA particularly for preterm infants is considered within the skill of artisan since the criticality of ARA and DHA for preterm infant growth is known in the art. Note the claimed ratio of ARA:DHA is within the broad range claimed by Kyle. See, particularly, claim 20 in Kyle.

Response to the Arguments

18. Applicants' remarks submitted February 19, 2002 have been fully considered, but are not persuasive for reasons discussed below.

19. The applicants assert that the examiner fails to appreciate the difference between the "proper growth" in the prior art and "enhance growth" herein, and fails to appreciate the "surprising results" discovered by the applicants. In examining the claimed invention, the examiner does not need to do so. More specifically, the recitation "enhancing the growth" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The instant claims are directed to an old or obvious method or composition. The argument that such claims are not directed to the old and well known ultimate utility (feeding preterm infants) for composition, e.g., ARA and DHA enriched

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formula, are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various functions (enhancing growth). The ultimate utility for the claimed ARA and DHA enriched formula is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang
April 28, 2002